

Sugano
B1/CN1

in a second part comprising less than two percent by aggregate weight of ester isomers selected from the group consisting of 8,10-octadecadienoic acid alkyl esters, 11,13-octadecadienoic acid alkyl esters, and trans,trans-octadecadienoic acid alkyl esters, and in a third part comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid.

R E M A R K S

Applicants thank the Examiner for removing the enablement rejections. Claims 1-8 are at issue in the present application. The Claims stand rejected under 35 U.S.C. §103, as allegedly being obvious over U.S. Pat. Nos. 5,554,646 and 5,428,072 (the Cook patents). Applicants believe the present amendments and following remarks traverse the Examiner's rejection of the Claims.

I. The Examiner has Not Established a *Prima Facie* Case of Obviousness

A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue. See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990). The Examiner has failed to establish a *prima facie* case of obviousness because the threshold requirements for *prima facie* obviousness have not been met.

A. The Combined References Do Not Teach Each Element of the Claims

The cited references do not teach each element of the Claims. The Examiner states that he has considered Applicants' amendments and remarks. However, the Examiner has failed to address the teachings of the Sugano reference¹ submitted with the Response and

¹ Sugano *et al.*, "Conjugated Linoleic Acid Modulates Tissue Levels of Chemical Mediators and Immunoglobulins in Rats," *Lipids*, 33(5):521-27 (1998).

Amendment dated March 28, 2000. Applicants' reiterate their argument that the Cook patents **do not teach the composition of the CLA** produced by the methods taught in the Cook patents. The Examiner admits as much by stating that "it is noted that the cited prior art does not disclose the presence of any significant amounts of isomers such as the 8,10- and 11-13-isomers of conjugated linoleic acid in the compositions therein."

Comparison of the Sugano reference and the Cook patents reveals that Sugano prepared CLA from purified linoleic acid by a method similar to that utilized by Cook. In both methods, conjugation was performed in ethylene glycol at 180°C. The main differences are that the Cook patents utilize NaOH as the catalyst, as opposed to the KOH used by Sugano, and that the Cook patents heated the mixture for 2.5 hours, as opposed to the 2.0 hours used by Sugano. Sugano discloses that their CLA contained **18.6%** trans-trans isomers and **13.7%** other isomers, in addition to the c9,t11 and t10,c12 isomers. Applicants fail to understand how the Cook patents allegedly teach the "less than 2% of 8,10, 11,13 and trans-trans isomers of CLA" element of the claims when it is clear that methods similar to those utilized by Cook result in a **much different composition**.

The Examiner does not cure this deficiency by stating that "purification of each individual isomer of conjugated linoleic acid is considered within the skill of the artisan, absent evidence to the contrary." Applicants respectfully submit that the Examiner is not one skilled in the art and is required to present support for this proposition.²

The Examiner further states that the Cook patents teach "a active form of conjugated linoleic acid, i.e., 10,12-octadecadienoic acid and 9,10 octadecadienoic acid, which including ester, salt and free acid of conjugated linoleic acid" and that "c9,t11 and t10,c12 isomer are predominantly major isomer of the conjugated linoleic acid active form of Cook '646."³ Applicants note that the portions of the Cook patents to which the Examiner cites contain disclosure concerning "active" isomers of CLA. As such, these sections **do not** rule out or otherwise address the fact that the compositions obtained by Cook *et al.* contain other isomers. For example, at Column 4, lines 1-9 Cook *et al.* specify that:

² See MPEP 2144.03.

³ Office Action, page 2.

The animal feeds and pharmaceutical or veterinary compositions for use in the method of the present invention are those containing the active forms of the free conjugated linoleic acids (CLA), especially the 9,11-octadecadienoic acid and 10,12 octadecadienoic acid or mixtures thereof

Furthermore, at Column 4, lines 50-55, Cook *et al.* specify:

Theoretically, 8 possible geometric isomers of 9,11 and 10,12-octadecadienoic acid (c9,c11; c9,t11; t9,c11; t9,t11; c10,c12; c10,t12; t10,c12; and t10,t12) would form from the isomerization of c9,t12-octadecadienoic acid. As a result of the isomerization, only four isomers (c9,c11; c9,t11; t10,c12; and c10,c12) would be expected.

These passages are only directed to the so-called "active" isomers of CLA. These passages do not address all of the other isomers that are commonly formed when linoleic acid is isomerized. The existence of the other isomers in isomerized linoleic acid compositions is documented in the Sugano reference discussed above and in Examples 1-3 of the present application. Applicants contend that these passages from Cook do not teach a composition containing only active isomers as the Examiner suggests. They simply discuss the so called "active" isomers of CLA. Therefore, the Examiner's reliance on these passages as teaching a composition containing "zero percent"⁴ of the 8,10 and 11,13 isomers is unfounded.

For the reasons discussed above, Applicants respectfully submit that the cited references do not teach each element of the claims. As such, Applicants request that the obviousness rejection be removed and the claims passed to allowance.

B. The Cited References do not Provide Reasonable Expectation of Success

The cited references do not provide a reasonable expectation of success for obtaining the claimed compositions. The Federal Circuit has held that "obvious to experiment" is not the standard for obviousness. *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988). The Dow court made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art." *Id.* at 1531 (Emphasis added).

Applicants submit that one skilled in the art would not believe that a reasonable expectation of success existed for making the claimed CLA composition. The Examiner

⁴ Office Action, page 3.

states that "applicants have not demonstrated any unexpected results, e.g., in the purity of isomers useful herein over the prior art." Applicants respectfully submit that the above comparison of the Sugano reference and Cook patents presents ample evidence that Applicants achieved an unexpected result in producing CLA comprising less than 2% of 8,10, 11,13 and trans-trans isomers of CLA.

The Examiner also states that "[a] person of ordinary skill in the art would have been motivated to make a conjugated linoleic ester mixture comprising predominantly c9,t11- and t10,c12-octadecadienoic ester without/or less than 2% of 8,10- and 11,13-octadecadienoic acid ester and employ the mixture in animal feed because 8,10- and 11,13- octadecadienoic esters are known not to be required in the active form of conjugated linoleic acid and the c9,t11 and t10,c12 ester mixture is known to be useful in animal feeds."⁵ First, Applicant's request that the Examiner provide support for the proposition that "8,10- and 11,13- octadecadienoic esters are known not to be required in the active form of conjugated linoleic acid." Absent such support, Applicants respectfully request that this statement be withdrawn. Second, Applicants contend that the Cook patents provide absolutely no guidance or suggestion as to whether the 8,10 and 11,13 isomers of CLA should be minimized in the product and, indeed, how to actually minimize these isomers. As discussed above, the disclosure of the Cook patents is primarily directed to the 9,11 and 10,12 isomers of CLA. The existence of the other isomers is ignored. Therefore, Applicants fail to understand how the Cook patents allegedly provide a reasonable expectation of success in producing the claimed compositions when the Cook patents neither discuss the 8,10 and 11,13 isomers or provide methods for reducing their concentration in CLA compositions.

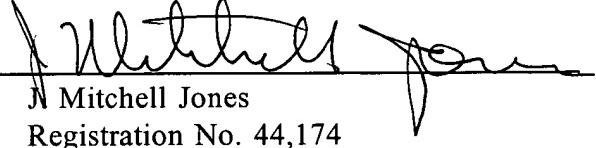
Accordingly, Applicants respectfully submit that the Examiner has not established a reasonable expectation of success for making the claimed invention. Therefore, Applicants request that the obviousness rejection be removed and the claims passed to allowance.

⁵ Office Action, page 3.

CONCLUSION

All grounds of rejection of the Office Action of June 21, 2000 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call Mitchell Jones collect at (608) 218-6900.

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